

Notice of Allowability

Application No.

09/750,779

Examiner

Dave T. Nguyen

Applicant(s)

LI ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/26/04.
2. ☒ The allowed claim(s) is/are 5, 7-8, 10-14, 16-17, 19-23, 25-26, 28-32, 34-35, 37-42, and 44-46.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date 12/18/02.
 - (b) ☐ Including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 2/26/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Feb 26, 2004 has been entered.

Claims 1-5, 7-8, 10-14, 16-17, 19-23, 25-26, 28-32, 34-35, 37-42, and 44-46 are pending.

All of the references in the IDS dated Feb 26, 2004 have been considered. The JP 11-316225 has been considered only to the extent that the abstract in English language has been provided. The claims remain allowable. The examiner acknowledges that the latest references, for example, reference WO 00/62830 and WO 99/08729, together with the examiner's newly cited references, e.g., US 6,589,546, and US 6099562, do teach the concept of employing alternating layers of a barrier layer of unloaded polymeric materials, and a layer of a drug such as a negatively charged drug, the references of record do not teach, suggest, or provide a motivation to employ a multiplicity of alternating and inner layers of a cationic polyelectrolyte carrier (albumin, gelatin, chitosan), a and a multiplicity of alternating and outer layers of a negatively charged therapeutic agent (rapamycin, DNA), whereby the multiplicities of alternating layers adsorbed to the surface of a medical device function as to both maximize the amount of a negative therapeutic agent that can be adsorbed to the medical device and control the release of the therapeutic agent at a target site (page 7, the specification).

Art Unit: 1632

WO 00/62830 teaches several layers of a drug-polymer(1) and drug-polymer (2) or of a drug-polymer based layer and an albumin based layer served as an outer layer to enhance the surface biocompatibility (page 24). However, the '830 reference neither teaches the make and use of a multiplicity of alternating and inner layers of a cationic polyelectrolyte carrier and a multiplicity of alternating and outer layers of a negatively charged therapeutic agent, nor suggests the make and use of a cationic polyelectrolyte based layer as the first or initial layer adsorbed to an insertable medical device. In other words, WO 00/62830 does not recognize or disclose the importance of having multiple and alternating layers served as alternating inner layers to maximize the entrapment of negatively charged therapeutic agents. Likewise, US 6,589,546, and US 6,099,562 while teach the use of a barrier layer of a polymer to control the release of a drug, which may include a negatively charged drug, do not teach the make and use of a multiplicity of alternating and inner layers of a cationic polyelectrolyte carrier and a multiplicity of alternating and outer layers of a negatively charged therapeutic agent, and do not suggest the make and use of a cationic polyelectrolyte based layer as the first or initial layer adsorbed to an insertable medical device. The international search report attached to the IDS also has been considered, however, the report while being relevant to the originally filed claims as set forth in the PCT application, does not provide any evidence so as to anticipate and/or render the currently pending claims unpatentable. As such, all presently pending claims remain allowable.


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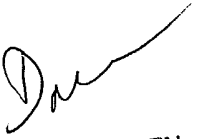
Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Amy Nelson*, may be reached at **571-272-0804**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center number, which is **703-872-9306**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.


DAVE T. NGUYEN
PRIMARY EXAMINER

Dave Nguyen
Primary Examiner
Art Unit: 1632